ARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

April 9, 2009

Richard J. Meelia
Chairman, President and Chief Executive Officer
Mallinckrodt Inc. Pharmaceuticals Group
675 McDonnell Blvd.
St. Louis, MO 63134

Product:
Morphine Sulfate Concentrate Oral Solution 20mg/ml

Dear Mr. Meelia:

This letter is written in reference to the March 30, 2009 warning letter (Warning Letter) your firm received for manufacturing morphine sulfate oral solution 20 mg/ml, an unapproved new drug, in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

The mission of FDA's Center for Drug Evaluation and Research (CDER) is to assure that safe and effective drugs are available to the American people. The drug approval system is one of the essential means by which CDER achieves its mission and ensures that patients have access to prescription drugs of proven safety, efficacy, and quality.

FDA remains committed to taking enforcement actions against unapproved drugs in an effort to ensure that drugs used by patients are safe and effective, while at the same time ensuring that such actions do not impose an undue burden on patients. Currently, there are no approved morphine sulfate oral solution 20 mg/ml products being marketed in the U.S. FDA has heard from the pain management community that the impending market removal of unapproved morphine sulfate oral solution 20 mg/ml products announced in the Warning Letter would impose extreme hardship on palliative care patients and their families. In light of this information, FDA intends to extend the period of enforcement discretion set forth in the Warning Letter to ensure that palliative care patients have access to morphine sulfate oral solution 20 mg/ml.

The period of enforcement discretion set forth in the Warning Letter will be extended until 180 days after any firm receives approval for a morphine sulfate oral solution 20 mg/ml product. If your firm manufacturers an unapproved morphine sulfate oral solution 20 mg/ml beyond the date that is 180 days after the date of such

an approval, that activity may result in legal action without further notice, including, without limitation, seizure and injunction. The extension of this period of enforcement discretion will not apply if FDA determines that your firm is violating other provisions of the Act or identifies additional safety information, or if FDA determines that alternative medications become available that could meet the needs of palliative care patients. FDA is actively evaluating alternatives to morphine sulfate oral solution 20 mg/ml and working with firms to expedite approval of such products. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations. Please be advised that we are not extending the period of enforcement discretion for any other products identified in the Warning Letter; the period of enforcement discretion stated in the Warning Letter will continue to apply to those other products.

Furthermore, FDA reiterates its expectation that all firms that market unapproved drugs to the American public submit the required applications to obtain approval for those products. FDA intends to continue to take aggressive enforcement action against marketed unapproved drugs.

FDA understands the need to continue to provide assistance to firms and to help them secure approval for unapproved drugs they are currently marketing. As part of this commitment, FDA appointed an unapproved drugs coordinator in the Office of New Drugs, Dr. Sally Loewke, to work with companies trying to bring their products into compliance. Please contact Parinda Jani, Chief Project Manager, Office of New Drugs, at 301-796-1232, about obtaining the necessary approval for your unapproved morphine sulfate oral solution 20 mg/ml drug product or any other unapproved product you may be marketing.

FDA is committed to making sure that patients have access to drugs of proven safety, efficacy, and quality and hopes that your firm shares this same commitment. If you have any additional questions concerning this letter, please contact Ms. Sakineh Walther, Compliance Officer, at the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, HFD-310, WO51 RM 542, 10903 New Hampshire Avenue, Silver Spring, MD 20993.

Sincerely,

/Deborah M. Autor/
Deborah M. Autor, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration